MEDICAL LABORATORY SCIENCE COUNCIL OF NIGERIA

MEDICAL LABORATORIES: REGULATIONS FOR INSPECTION, APPROVAL,MONITORING AND ACCREDITATION[S.4 & 7 of MLSCN 2003 ACT No. 11]

DECEMBER 2012

FOREWORD

The World Health Organization (WHO) recognizes quality laboratory services as key to improving global health and attaining the Millennium Development Goals. Strengthening the breadth of laboratory services accessible to clients, and ensuring that results are accurate, reliable, reproducible, and rapid enough to be useful, is crucial to improved health outcomes.

Until recently, however, the majority of public health laboratories in Nigeria delivered suboptimal services and were not in a position to contribute to a quality health system. Many performed poorly, hindered by dilapidated infrastructures, poor development and implementation of Quality Management Systems (QMS), including inadequate participation in External Quality Assessment (EQA) programs.

The Medical Laboratory Science Council of Nigeria (hereinafter referred to as 'Council') under section 4(h) and 19(d) of MLSCN Act, 2003 is mandated to inspect, approve, monitor and accredit Medical Laboratories in the country. Council accreditation is a validation process established to ensure that Medical Laboratories deliver high quality services that meet the needs and requirements of their clients. It also demonstrates competence and impartiality while promoting national and international recognition. At present, through strong commitment and leadership by the Federal Ministry of Health (FMOH), the Medical Laboratory Science Council of Nigeria (MLSCN) in collaboration with international partners (CLSI, CDC) has adopted the ISO 15189 standard to improve the quality of medical laboratory services in Nigeria.

This document has been developed to regulate the accreditation processes of Medical Laboratory Services in Nigeria to ensure accuracy, reliability and sustainability in the quality of service delivery.

I therefore encourage all stakeholders both in public and private health sectors at all levels in Nigeria to use this document in the improvement of quality of laboratory services.

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Acknowledgment

The MLSCN sincerely appreciates the efforts of all that contributed to the successful development of this document.

We appreciate the tremendous efforts of the United States Government through US Centers for Disease Control and Prevention (CDC) for funding the MELTNA (Mentoring Laboratories towards National Accreditation) project. We also appreciate the technical and logistics support of all CDC, USAID and DOD implementing partners.

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Arrangement of Regulations

In exercise of the powers conferred on the Governing Board by Sections 4, 7 & 19 of the Medical Laboratory Science Council of Nigeria Act, No. 11, 2003, the Board hereby makes the following regulations.

[DATE OF COMMENCEMENT……..]

1. POWERS TO INSPECT, MONITOR, EVALUATE & ACCREDIT:

The Council shall have power to inspect, monitor, evaluate and accredit Medical Laboratories to ensure the maintenance of good standard of Medical Laboratory practice, international best practices, improving and strengthening the capacity and quality of services of the Medical Laboratories.

2. INSPECTION, APPROVAL AND MONITORING OF MEDICAL LABORATORIES

1) The Council shall conduct periodic inspection and approval for registration of medical laboratories.

2) The Council shall also conduct periodic monitoring of registered Medical Laboratories' operations to ensure continuity in standard.

3) There is hereby established for the council:
   a. An Inspection Team
   b. A monitoring team

Which shall consist of such number of persons as the Council may deem fit to appoint.

4) The Inspection Team shall carry out periodic inspection activities on Medical Laboratories

5) The Monitoring Team shall conduct regular monitoring and evaluation of Medical Laboratories.

6) No Medical Laboratory, its staff, the owner/proprietor (Practitioner or non-Practitioner) or person(s) acting through or for him shall prevent, deter or refuse the inspection and Monitoring Team of the Council from carrying out its exercises.

7) Where any Medical Laboratory or the Practitioner/Owner permits, allows or authorizes directly or indirectly any staff or person(s) acting through or for him to act contrary to the provision in subsection 6 above, such a Medical Laboratory or Practitioner/Owner shall be held to have committed an offence under these Regulations.

8) Where an Inspection Team conducts an inspection of a Medical Laboratory and such Medical Laboratory fails to meet up to 40% (forty Percent) of the requirements listed on the checklist, it shall be closed and sealed by Council and the Medical Laboratory given at most six months period to regularize its status.

9) The Inspection Team upon the conclusion of an inspection visit shall forward a report of its findings inclusive of recommendations to the Council.

10) Where the Medical Laboratory is ready to regularize its status, it shall forward an application to the Registrar of Council requesting for temporary access to the Medical Laboratory to enable it carry out the recommendations of the Inspection Team.

11) Upon the expiration of the time stated in subsection (8) above, a Monitoring Team shall be sent by the Council in the appropriate jurisdiction to ensure compliance with the recommendations made by the Inspection Team to the Medical Laboratory.

12) Where the Monitoring Team conducts a visit on a Medical Laboratory or receives information that such a Medical Laboratory is operated by a person who is not a member of the profession but who holds himself out to the public as a member

of the profession and/or is operated by a Medical Laboratory Scientist below professional standard or against best practices, the Monitoring Team shall upon confirmation, close and seal the Medical Laboratory.

13) The Council's Zonal Offices and State Offices shall conduct routine monitoring visits before and after inspection visits on Medical Laboratories within their jurisdiction.

14) Any hospital that desires to set up a medical laboratory or a side laboratory for point of care testing (POCT) shall observe Council's guidelines as contained in Schedule 1 of these regulations.

3. PROCEDURE FOR ACHIEVING THE 5-STAR TIERED NATIONAL CERTIFICATION /ACCREDITATION APPROACH

1) Every Medical Laboratory that applies for certification or accreditation shall be subjected to a baseline assessment of laboratory operating procedure and practices.

2) The national accreditation checklist shall be used for the baseline assessment.

3) Where a Medical Laboratory's performance is abysmal, or achieves less than the passing score on any one of the applicable criteria, it will be subject to mentoring by Council's Continual Quality Improvement to -
   a. Identify areas where improvement is needed.
   b. Develop and implement a work plan.
   c. Monitor Medical Laboratory progress.
   d. Provide for inter-laboratory comparison and/or re-testing where CLSI is unavailable.
   e. Continue steps to achieve full accreditation.

4) A Medical Laboratory that has regularized its status after mentoring can apply to the Council for accreditation.

5) The number of stars awarded to a Medical Laboratory from the laboratory audit checklist in the 5 star tiered certification approach will be in the following manner-

No STAR (0-142pts) <55%	1 STAR (143-165pts) 55-64%	2 STARS (166-191pts) 65-74%	3 STARS (192-217pts) 75-84%	4 STARS (218-243pts) 85-94%	5 STARS (244-258pts) ≥95%

6) A Medical Laboratory that has achieved the 5 star status, can proceed to apply for national accreditation if it so desires.

7) Where a Laboratory scores below the 5-star status, it shall be certified at the appropriate star status commensurate to its scored mark.

8) A Laboratory that scores below 5-star status shall be placed in a mentorship programme by Council for at least 6(six) months after which it shall invite Council to conduct another assessment. This mentorship process should continue until such Laboratory remedies the deficiencies to attaining the 5-star status and qualifies for accreditation.

4. CONTINUING QUALITY IMPROVEMENT/MENTORSHIP PROGRAMME

1) The Council shall conduct continuing quality improvement / mentorship programme for Medical Laboratories.

2) The CQI is mandatory for accreditation. Registered Medical Laboratories that do not wish to be accredited should enroll for the purpose of improving the quality of services offered to the public.

5. CRITERIA FOR CONTINUING QUALITY IMPROVEMENT/MENTORSHIP PROGRAMME

1) There will be a baseline assessment.

2) The Medical Laboratory will undergo corrective action based on observed non-conformances and conduct competency improvement trainings for personnel.

3) The Medical Laboratory is to obtain appropriate application forms and relevant checklists.

4) The appropriate fees as prescribed by Council will be paid by the consigned laboratory.

6. STANDARD FOR ACCREDITATION

1) The Accreditation shall be conducted in conformity with the National Standard for accreditation of Medical laboratories.

2) The National Accreditation Checklist will be based on International Organization for Standardization ISO 15189:2012 (E) and to a lesser extent, CLSI guidelines GP26 – A3.

7. CRITERIA FOR ACCREDITATION

1) Any Medical Laboratory that is desirous of accreditation is expected to fulfill the following requirements:-
a) The Head/Director of the Medical Laboratory and all staff/personnel in the Medical Laboratory involved in the processing of samples for diagnostic purposes must be appropriately qualified Medical Laboratory personnel with qualifications registerable with the Council.

b) The Medical Laboratory shall have appropriate ratio of support staff to Medical laboratory scientist.

c) All components of the Quality Assurance must be current and operational.

d) The Laboratory must be registered and participate in an External Quality Assurance Program within the last 6 months.

e) Documentation (SOPs, Manuals, policies, guidelines, Records etc) of the Medical Laboratory facility must be in place.

f) The Medical Laboratory must have its safety policies (staff, environment, sample collection, waste management etc) in place.

g) The Medical Laboratory must provide documentary evidence of fulfillment of the above guideline prior to inspection and accreditation.

h) Obtain appropriate application forms upon the payment of a fee.

i) Pay the Prescribed Laboratory Assessment fee as may be fixed by Council.

j) Provide proof of annual retention fee as may be fixed by Council.

k) The Medical Laboratory personnel shall have their current license/identification tag to practice.

l) The Medical Laboratory should have obtained the 5-star tiered national certification in its previous site assessment.

m) The Medical laboratory specimen should meet at least 80% of turnaround time (TAT).

n) Internal quality control should be practiced for all testing methods used in the laboratory

o) The medical laboratory must score 80% or more on the most two recent proficiency testing.

p) The Medical Laboratory must have a well-defined operational organogram.

q) All basic and assay specific Laboratory equipment must be appropriately and satisfactorily housed in the facility.

r) All equipment must be appropriately calibrated and standardized for the performance of appropriate Laboratory investigation that it was installed to carry out.

s) Schedule of equipment preventive maintenance must be in place and maintained as at when due and must be documented.

8. HUMAN RESOURCES REQUIREMENT FOR APPROVAL, MONITORING AND ACCREDITATION OF MEDICAL LABORATORY

The human resource competencies, technical knowledge and expertise needed for effective Laboratory service delivery in the health sector is specified as follows.

1) At each level of healthcare, the laboratory shall be staffed by adequate number of properly trained personnel to deliver adequate and quality laboratory services.

2) In depth practical instruction in approved Medical Laboratory institutions or establishments shall be an integral part of training of all cadres of medical laboratory staff.

3) All medical laboratory staff shall be certified by the Medical Laboratory Science Council of Nigeria.

4) The Medical Laboratory Science Council of Nigeria shall maintain a database of all categories of certified laboratory staff.

5) The laboratory human resources capacity needs to be standardized by aligning the numbers of trained laboratory personnel with clinicians and other health staff to ensure comprehensive, quality health service delivery.

6) Continuing professional education with support in the work place (competence based task oriented) is required to retain the competence and motivation of laboratory staff personal development.

9. APPLICATION FOR ACCREDITATION

Any Medical Laboratory that is desirous of accreditation shall apply to the council by forwarding a completed application form upon the payment of a fee as may be prescribed by Council. .

10. ACCREDITATION OF MEDICAL LABORATORIES

1) Council accreditation is a validation process established to ensure medical laboratories deliver high quality services that meets the needs and requirements of their clients. It demonstrates competence, impartiality, and performance capability, national and international recognition.

2) Any Medical Laboratory that is registered with the Council may, if it so desires, apply to the Council for its accreditation.

3) Upon successful completion of the inspection, monitoring and certification process, the Medical laboratory is awarded Council's accreditation and becomes part of an exclusive

group of laboratories nationally that have met the highest standards of excellence.

11. LIFE SPAN FOR ACCREDITATION

The life time of accreditation after partnering with Council for quarterly improvement is three (3) years from date of approval by the Independent Advisory Committee of Council.

12. 14. PENALTY

1) Where a Medical Laboratory or a practitioner or person(s) acting through or for him contravenes any provisions of these regulations; deliberately breaks the seal of Council placed on a sealed Medical Laboratory for purposes of commencing routine business without fulfilling the recommendations of the Monitoring Team, he is guilty of an offence and is liable on conviction to a fine of Two Hundred Thousand Naira (N200, 000.00) only or one year imprisonment or both.

2) In addition, if the Person who commits the offence in subsection (1) is a Medical Laboratory Scientist, the Council may withdraw his license for a period of six (6) months or pending such time that the offender meets with the recommendations of the Monitoring Team and satisfies requirement by Council

13. 15. INTERPRETATION

For the purpose of these Regulations, unless the context otherwise requires-

“Council”	-	Medical Laboratory Science Council of Nigeria or the Governing Board of the Medical Laboratory Science Council of Nigeria
“Practitioner'	-	Medical Laboratory Scientist
“CQI"	-	Continuing Quality Improvement

"SOP"	-	Standard Operating Procedure
"WHO-AFRO"	-	World Health Organization African Regional Office
"ISO"	-	International Standardization for Organization
"POCT"	-	Point of Care Testing
"TAT"	-	Turn Around Time
"CLSI"	-	Clinical Laboratory Standards Institute

16. CITATION

These Regulations may be cited as Medical Laboratories (Inspection, Approval, Monitoring and Accreditation) Regulations.

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MLSCN REGULATION